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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,610	09/14/2006	Gillian Smith	03981/0203467-US0	6340
7278 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770	7590 12/27/2007		EXAMINER PAK, YONG D	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/552,610

Applicant(s)

SMITH ET AL.

Examiner

Yong D. Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/14/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7,15,16,18,20,21,23,25 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3,4,6,7,15,16,18,20,21,23,25 and 32-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application is a 371 of PCT/GB04/01453.

The preliminary amendment filed on September 14, 2006, amending claims 1, 3-4, 6-7, 15-16, 18, 20-21, 25, 32-38, canceling claims 2, 5, 8-14, 17, 19, 22, 24 and 26-31 and adding claim 39, has been entered.

Claims 1, 3-4, 6-7, 15-16, 18, 20-21, 23, 25 and 32-39 are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 4, 6-7 and 15-16, drawn to a method for identifying an agent capable of modulating expression of CYP2S1 using a cell comprising a CYP2S1 gene under the control of a regulatory sequence comprising at least of an XRE-like sequence, an AP-1 like sequence or a RARE-like sequence.

Group II, claim(s) 1, 3-4 and 6, drawn to a method for identifying an agent capable of modulating expression of CYP2S1 using a cell comprising a reporter gene under the control of a regulatory sequence comprising at least of an XRE-like sequence, an AP-1 like sequence or a RARE-like sequence.

Group III, claim(s) 18, 20-21 and 23, drawn to a vector comprising a polynucleotide capable of encoding CYP2S1 under transcriptional and/or translation control of the regulatory sequence shown in Figure 7, host cell comprising said vector and a method of producing CYP2S1.

Group IV, claim(s) 18 and 20, drawn to a vector comprising a polynucleotide capable of encoding a reporter protein under transcriptional and/or translation control of the regulatory sequence shown in Figure 7 and a host cell comprising said vector.

Group V, claim(s) 25, drawn to a composition comprising CYP2S1.

Group VI, claim(s) 32, drawn to a method of preventing in a subject a skin condition by administering the subject a CYP2S1.

Group VII, claim(s) 32, drawn to a method of treating in a subject a skin condition by administering the subject a CYP2S1.

Group VIII, claim(s) 32, drawn to a method of ameliorating in a subject a skin condition by administering the subject a CYP2S1.

Group IX, claim(s) 32, drawn to a method of preventing in a subject a skin condition by administering the subject a vector expressing CYP2S1.

Group X, claim(s) 32, drawn to a method of treating in a subject a skin condition by administering the subject a vector expressing CYP2S1.

Group XI, claim(s) 32, drawn to a method of ameliorating in a subject a skin condition by administering the subject a vector expressing CYP2S1.

Group XII, claim(s) 32, drawn to a method of preventing in a subject a skin condition by administering the subject an agent capable of modulating expression of CYP2S1.

Group XIII, claim(s) 32, drawn to a method of treating in a subject a skin condition by administering the subject an agent capable of modulating expression of CYP2S1.

Group XIV, claim(s) 32, drawn to a method of ameliorating in a subject a skin condition by administering the subject an agent capable of modulating expression of CYP2S1.

Group XV, claim(s) 33, drawn to a method of diagnosing a skin condition by detecting a level of CYP2S1.

Group XVI, claim(s) 33, drawn to a method of diagnosing a predisposition to a skin condition by detecting a level of CYP2S1.

Group XVII, claim(s) 34, drawn to a method of diagnosing a skin condition by detecting expression of CYP2S1.

Group XVIII, claim(s) 34, drawn to a method of diagnosing a predisposition to a skin condition by detecting expression of CYP2S1.

Group XIX, claim(s) 35-36, drawn to a method detecting effectiveness of a skin treatment by detecting the level of CYP2S1.

Group XX, claim(s) 37, drawn to a method of identifying a new skin treatment drug candidate by contacting a drug candidate with CYP2S1.

Group XXI, claim(s) 38, drawn to a method of improving effectiveness of a skin treatment by detecting the level of CYP2S1.

Group XXII, claim(s) 39, drawn to a method detecting level of CYP2S1.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XXII appears to be that they all relate to a CYP2S1.

However, Rylander et al. (Biochem Biophys Res Commun. 2001 Feb 23;281(2):529-35 – form PTO-892) discloses CYP2S1 (abstract).

Therefore, the technical feature linking the inventions of Groups I-XXII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is a method for identifying an agent capable of modulating expression of CYP2S1 using a cell comprising a CYP2S1 gene under the

control of a regulatory sequence comprising at least of an XRE-like sequence, an AP-1 like sequence or a RARE-like sequence.

The special technical feature of Group II is a method for identifying an agent capable of modulating expression of CYP2S1 using a cell comprising a reporter gene under the control of a regulatory sequence comprising at least of an XRE-like sequence, an AP-1 like sequence or a RARE-like sequence.

The special technical feature of Group III is a vector comprising a polynucleotide capable of encoding CYP2S1 under transcriptional and/or translation control of the regulatory sequence shown in Figure 7, host cell comprising said vector and a method of producing CYP2S1.

The special technical feature of Group IV is a vector comprising a polynucleotide capable of encoding a reporter protein under transcriptional and/or translation control of the regulatory sequence shown in Figure 7 and a host cell comprising said vector.

The special technical feature of Group V is to a composition comprising CYP2S1.

The special technical feature of Group VI is a method of preventing in a subject a skin condition by administering the subject a CYP2S1.

The special technical feature of Group VII is to a method of treating in a subject a skin condition by administering the subject a CYP2S1.

The special technical feature of Group VIII is a method of ameliorating in a subject a skin condition by administering the subject a CYP2S1.

The special technical feature of Group IX is a method of preventing in a subject a skin condition by administering the subject a vector expressing CYP2S1.

The special technical feature of Group X is a method of treating in a subject a skin condition by administering the subject a vector expressing CYP2S1.

The special technical feature of Group XI is a method of ameliorating in a subject a skin condition by administering the subject a vector expressing CYP2S1.

The special technical feature of Group XII is a method of preventing in a subject a skin condition by administering the subject an agent capable of modulating expression of CYP2S1.

The special technical feature of Group XIII is a method of treating in a subject a skin condition by administering the subject an agent capable of modulating expression of CYP2S1.

The special technical feature of Group XIV is to a method of ameliorating in a subject a skin condition by administering the subject an agent capable of modulating expression of CYP2S1.

The special technical feature of Group XV is to a method of diagnosing a skin condition by detecting a level of CYP2S1.

The special technical feature of Group XVI is a method of diagnosing a predisposition to a skin condition by detecting a level of CYP2S1.

The special technical feature of Group XVII is a method of diagnosing a skin condition by detecting expression of CYP2S1.

The special technical feature of Group XVIII is a method of diagnosing a predisposition to a skin condition by detecting expression of CYP2S1.

The special technical feature of Group XIX is a method detecting effectiveness of a skin treatment by detecting the level of CYP2S1.

The special technical feature of Group XX is a method of identifying a new skin treatment drug candidate by contacting a drug candidate with CYP2S1.

The special technical feature of Group XXI is a method of improving effectiveness of a skin treatment by detecting the level of CYP2S1.

The special technical feature of Group XXII is a method detecting level of CYP2S1.

Accordingly, Groups I-XXII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Application/Control Number:  
10/552,610  
Art Unit: 1652

Page 7

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).



Yong D. Pak  
Patent Examiner 1652